

Application No. 10/559,996  
AMENDMENT D  
Reply to Office Action of February 18, 2010

**REMARKS/ARGUMENTS**

Claims 1-21 are pending in this application, of which claims 4-12 and 15-20 are currently withdrawn from consideration. Claims 1 and 21 are the pending independent claims.

While Applicants believe that such amendment is unnecessary, claim 21 is amended herein to state that the residues of formula IIa are terminal groups. Support for this amendment can be found at, for example, the structures of Examples 2 and 3 of the specification as originally filed.

**Substance of the Interview**

Applicants' attorneys thank Examiner Ronald Niebauer and Examiner Anish Gupta for the telephone interview on July 14, 2010 with Applicants' attorneys, Tim Levstik and Calista Mitchell. During the interview, the Rathore and Biessen references were discussed. The claim terms "residue" and "binding group Y" were also discussed.

**Rejections of Claims 1-3, 13-14, and 21 under 35 U.S.C. § 102(b)**

Claims 1-3, 13-14, and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Rathore et al. and Biessen et al. (WO 94/04545).

Applicants attach to this Response two charts prepared for and given to Examiner Niebauer for the telephone interview on July 14, 2010.

**Rathore et al.**

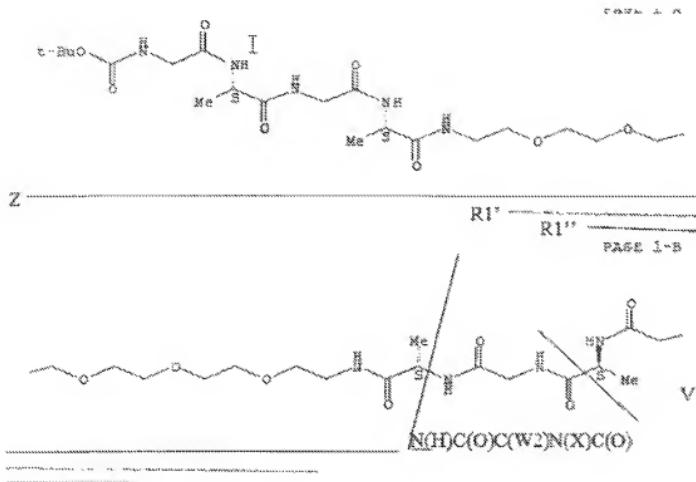
The residues of formula II(a) as claimed herein are terminal residues, whereby binding takes place via the  $\text{CH}_2\text{-CH}_2\text{-}$  group, since  $R_1$  is a terminal group selected from hydrogen, hydroxyl or a hydrocarbon residue which has from 1 to 10 carbon atoms and optionally contains heteroatoms. As no further bond is shown on  $R_1$  and because  $R_1$  has a defined identity which would be meaningless if further residues were permitted adjacent  $R_1$  (i.e., on the end of  $R_1$  opposite the  $(\text{CH}_2\text{-CH}_2\text{-O})_n$  portion of the formula), formula IIa is clearly a terminal group and not a linking group. Applicants respectfully submit that the Examiner's interpretation of

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“comprising” is overly broad.

Applicants also respectfully disagree with the Examiner that the claims are not drawn to two independent and non-overlapping occurrences of formula IIa. While Applicants agree that claims are entitled to the broadest reasonable interpretation, such broad interpretation cannot render claim terms meaningless or which ignores other claim limitations. Indeed, as indicated at page 6 of the Office Action, the Examiner counts the same residue three times in order to meet the claim limitation that the compound comprises three residues which have formula IIa (dependent claim 3). Applicants respectfully submit that counting the same residue multiple times is simply not a reasonable interpretation of the claim. For example, if a claim was directed to a composition comprising a three carbon residue, a six carbon residue, and a nine carbon residue, Applicants submit it would be improper to cite a reference as anticipatory which describes a composition consisting of a nine carbon chain because such an interpretation would ignore the limitations directed to the three carbon and six carbon residues. However, that is precisely the improper interpretation given to the pending claims by the Examiner.

As explained in greater detail below, Rathore et al. does not include a compound having R<sub>1</sub> as claimed. The marked up compound provided by the Examiner at page 6 of the Office Action does not show R<sub>1</sub> as a terminal group as claimed.



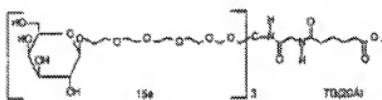
As claimed, formula (IIa) is  $(R_1 \cdot (CH_2 \cdot CH_2 \cdot O)_n \cdot CH_2 \cdot CH_2)$ . Therefore,  $R_1$  must be located adjacent  $(CH_2 \cdot CH_2 \cdot O)_n \cdot CH_2 \cdot CH_2$ . Rathore et al.'s formula 6 includes the following: Boc-GAGA-HN-(CH<sub>2</sub>-CH<sub>2</sub>-O)<sub>5</sub>-CH<sub>2</sub>-CH<sub>2</sub>-NH-AGAG-Boc. Solely because of its position adjacent - $(CH_2 \cdot CH_2 \cdot O)_5 \cdot CH_2 \cdot CH_2$ , the portion of Rathore et al.'s formula underlined above (Boc-GAGA-HN-) best corresponds to the portion labeled "R<sub>1</sub>" of formula IIa. However, as defined in the pending claims, R<sub>1</sub> is H, hydroxy or a hydrocarbon residue which has from 1 to 10 carbon atoms. As explained in more detail below, the Boc-GAGA portion of Rathore et al.'s formula has more than 1 to 10 carbon atoms. It should be noted that "Boc-GAGA" corresponds to N-*tert*-butoxycarbonyl-Gly-Ala-Gly-Ala. Therefore, Boc-GAGA includes the 10 carbons from the two Ala "A" residues (3 carbons each, or 6 carbons combined) and two Gly "G" residues (2 carbons), as well as the 5 carbons from the "Boc" group having the following structure:  $(CH_3)_3 \cdot C \cdot O \cdot CO \cdot \cdot$ . Therefore, Boc-GAGA provides 15 carbons, and therefore cannot meet the limitation of "where R<sub>1</sub> is H, hydroxy or a hydrocarbon residue which has from 1 to 10 carbon atoms" as

claimed.

Accordingly, for the numerous reasons listed above, the Rathore et al. reference does not describe or suggest the claimed invention.

Biessen et al.

Next, looking to Biessen et al., the Examiner cites compound TG(20A) of Biessen et al. as being of formula 1a as claimed. The Examiner states that Z includes the repeating structural element along with a CH<sub>2</sub> and then provides the following figure:



What the Examiner refers to as a CH<sub>2</sub> group indeed is only a carbon (adjacent the N-H outside of the bracketed portion) linked with the three bracketed structural elements. The Examiner states that the bracketed structural elements are repeats. Applicants respectfully disagree. Instead, Applicants respectfully submit that the formula depicts three independent occurrences of the bracketed element bonded to the same carbon atom, thus leaving that carbon atom without any hydrogen atoms. Accordingly, at best, Biessen has a O-CH<sub>2</sub> portion within the brackets which is adjacent the carbon outside of the brackets. Indeed, the linker shown by Biessen et al. is a formaldehyde acetal, not an ethylene oxide linker (O-CH<sub>2</sub>-CH<sub>2</sub>-) as found in formula 1a of the pending claims. Accordingly, the Biessen et al. compound does not meet the claims.

Accordingly, for at least the reasons discussed above, Applicants respectfully submit that Biessen et al. does not teach or suggest the claimed invention.

Double Patenting

Applicants will file a Terminal Disclaimer once the novelty and non-obviousness of the

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claimed invention has been acknowledged.

The Commissioner is hereby authorized to charge any additional fees which may be required in this application under 37 C.F.R. §§ 1.16-1.17 during its entire pendency, or credit any overpayment, to Deposit Account No. 06-1135.

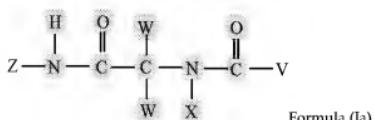
Respectfully submitted,  
FITCH, EVEN, TABIN & FLANNERY

Dated: July 19, 2010

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**Claim 1 of Pending Application:**



V, W, X and/or Z contains a binding group Y and the residues V, W, X and Z together comprise at least two residues which have formula (IIa)

$$R_1 = (CH_2-CH_2-O)_n - CH_2-CH_2-$$

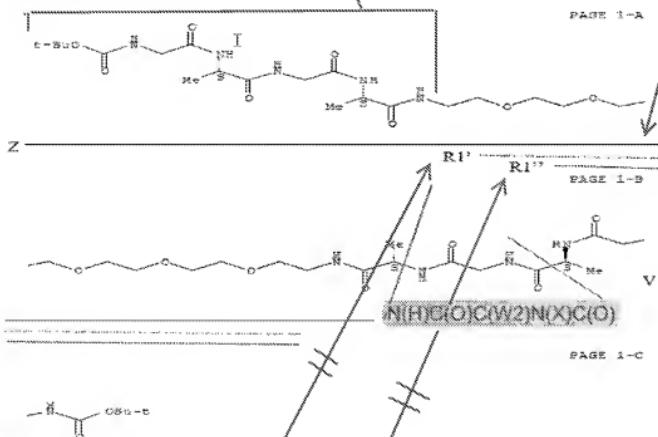
formula (IIa)

No, this terminal portion has  $> 10$  carbon atoms so it can't be R1

R<sub>1</sub> is H, hydroxyl or a hydrocarbon residue which has from 1 to 10 carbon atoms and which can contain heteroatoms, and

$n$  is, on each occasion independently, an integer of from 3 to 1000.

Rathore Prior Art Formula



Office Action at page 7 states as follows:

"In the instant case, Z comprises at least two residues which have formula IIa:  $\text{CH}_2\text{-O-CH}_2\text{CH}_2\text{O-(CH}_2\text{CH}_2\text{O)}_5\text{CH}_2\text{-O-H}_2$  (which is labeled as  $\text{R}_1$  above) where  $\text{R}_1$  is a hydrocarbon with 1 to 10 carbon atoms with heteroatoms as recited in the instant claims.

CH<sub>2</sub>-O-(CH<sub>2</sub>-CH<sub>2</sub>-O)<sub>3</sub>-CH<sub>2</sub>-CH<sub>2</sub> (which is labeled as R<sub>2</sub>" above) where R1 is a hydrocarbon with 1 to 10 carbon atoms with heteroatoms as recited in the instant claims."

Our response  $\Rightarrow$  No, for the following reasons:

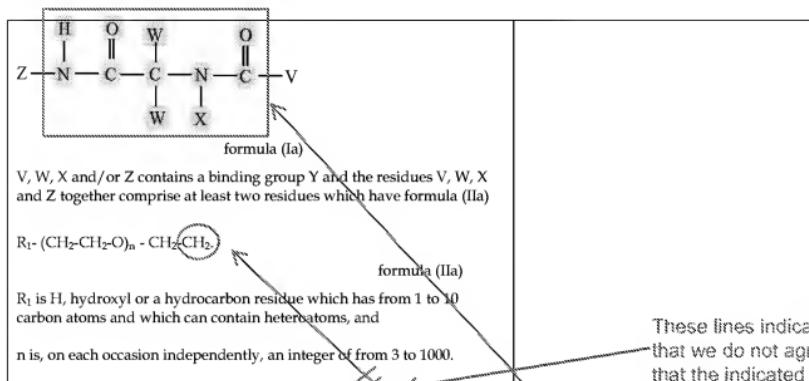
- R<sub>3</sub> is not terminal
- there are more than 10 carbons
- the Examiner is counting carbons 2x for different groups

This response is No, for the following reasons:

- R<sub>2</sub> is not terminal
- there are more than 10 carbons
- the Examiner is counting carbons 2x for different groups

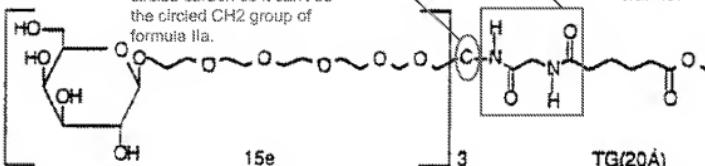
## COMPARISON OF CLAIM 1 TO BIJESSEN

**Claim 1 of Pending Application**



Biessen Prior Art

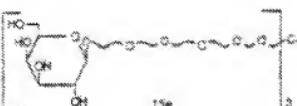
No. Biessen has three carbon chains branching from the circled carbon so it can't be the circled CH<sub>2</sub> group of formula IIa.



These lines indicate that we do not agree that the indicated portion of the cited reference meets the claims.

From the Office Action:

In comparison to the instant invention the compound of Biessen is of formula 1a of claims 1,21 of the instant invention. Specifically, Z includes the repeating structural element along with a CH<sub>2</sub>, that is Z is



If R1 is Z, the bracketed portion is more than 10 carbons.